

## International Federation of Societies of Toxicologic Pathologists IJF.S.T.P.

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4 May 1998

Dr. C.W. Jameson National Toxicology Program Report on Carcinogens MD EC - 14 P.O. Box 12233 Research Triangle Park, NC 27709

Re: Biennial Report on Carcinogens: National Toxicology Program: Saccharin Delisting

Dear Dr. Jameson,

The International Federation of Societies of Toxicologic Pathologists is a select federation of scientists representing societies of toxicologic pathology from eight countries or areas (Great Britain, Holland, France, Germany, Italy, Japan, the Scandinavian countries, and Canada-United States) which attempts to enhance the application in all countries of acquired scientific knowledge in product safety and risk assessment decisions. The Secretary General of the IFSTP has written to you in the past on the occasion of its triennial meeting in Tours, France, April 23-26, 1995 on the topic of "Risk Assessment of Carcinogens in Food with Special Consideration of non-Genotoxic Carcinogens."

Subsequent to this meeting, two documents were endorsed by all eight learned societies constituent members of IFSTP. The status of saccharin was part of these two endorsed documents, both of which stated that under "in-use" human saccharin exposures, no cancer risk would be predicted. Furthermore, due to differences in rat and human urinary conditions, humans would be less susceptible than rats to sodium saccharin-induced changes in the urinary bladder, and that the induction of urinary bladder tumors is species specific, namely to the experimental animals (rats) used.

We are concerned that, in spite of scientific evidence to the contrary, on last October 31, the NIEHS has released news that its Board of Scientific Counselors has recommended continuing the listing of saccharin as an anticipated human carcinogen. Few if any food additives have such an extensive database as saccharin in rodent and

subhuman primate bioassays, mechanistic animal research, and human epidemiological studies. All this research shows clearly that saccharin does not pose a carcinogenic hazard to man. Furthermore, The International Agency for Research on Cancer has likewise identified that the mechanisms involved in the induction of urinary bladder tumors by saccharin is species specific and not relevant to man.

IFSTP would like to bring to your attention how strongly the world community of toxicologic pathologists feels about the integrity of the scientific data and facts in the safety assessment of saccharin. We are confident that your decision will be based on the entire body of scientific evidence and only on the scientific evidence.

If you have any questions about the scientific recommendation of IFSTP, please contact either one of the signers of this letter.

Leander Tryphonas, DVM, PhD

C. Tryphones

**ACVP Diplomate** 

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